REMARKS

Status of the Claims

Claims 1-13, 15-22, 24-36, and 39-40 were pending. By way of this amendment, claims 1, 31, 34, 39, and 40 are amended and claims 41-76 are added. Therefore, claims 1-13, 15-22, 24-36, and 39-76 are pending.

Claims 31, 39, and 40 are amended to correct antecedent basis.

No new matter has been added.

The Declaration

The Examiner objected to the Declaration, as Applicant inadvertently omitted the first page from the Declaration filed July 7, 2008. Applicant submits with this paper a complete Declaration, addressing the objection.

Claim Rejections under 35 USC § 112

35 USC § 112, First Paragraph -- Written Description

The Examiner rejected claims 1-40[1] as allegedly failing to comply with the written description requirement, stating:

> *Claims 1 and 34 mention a uniform porosity, but the original disclosure described a range of pores that can be used on the membrane and the figures only show a portion of the pores.* (Office Action, page 2).

Applicant respectfully traverses.

[1] Applicant points out that claims 1-13, 15-22, 24-36, and 39-40 are pending. Applicant therefore proceeds as though the rejections under 35 USC §112 apply to claims 1-13, 14-22, 24-36, and 39-40.

The original disclosure contemplates that many different medical stent designs can be produced. (See, e.g., specification, page 8, lines 4-5.) The original disclosure states that one pattern may be selected over another in an effort to optimize those parameters that are of particular importance for a particular application. (See, e.g., specification page 8, lines 8-10.)

The original disclosure further describes that certain embodiments of the invention comprise stents for treating intracranial aneurysms. (See, e.g., specification, page 9, lines 17-29). The original disclosure describes embodiments of such stents having membranes that completely cover the stent, cover the midsection of the stent, or cover a radial section of the stent. (See, e.g. specification, page 18, lines 10-13, describing Figure 15.)

The original disclosure further states that perforations (i.e. perforators) refer to small vessels that have important and distinctive blood supply functions; and describes embodiments of stents that comprise a permeable membrane having a system of holes that: (i) allows blood supply into perforators and microscopic branches of cranial arteries and, simultaneously, (ii) does not allow blood supply into an aneurysm, though complete obstruction of blood penetration into the aneurysm may not be necessary. (See, e.g., specification, page 4, lines 10-12; specification, page 9, line 34 - page 10, line 1; page 15, lines 21-24; and page 17, lines 2-3.) The original disclosure states that such permeable stent membranes may have pore sizes between 20 to 100 μm, and that the distance between pores may be less than 100 μm. (See, e.g., specification, page 4, lines 12-15.)

The right side of Figure 10 illustrates a stent of the invention in which a porous membrane substantially covers the stent. Applicant submits that the right side of original Figure 10 demarks, in a square, a subsection of the membrane that is representative of the entire membrane. This is evident by the fact that the membrane in the figure shows a repeating geometric pattern that is substantially uniform in its distribution of material and openings across the length and width of the stent. The left side of Figure 10 illustrates a magnified view of the subsection, showing that the pores of the membrane have a substantially uniform distribution, shape, and size. Thus, the membrane depicted in Figure 10 clearly has a substantially uniform porosity.

In view of the foregoing discussion, Applicant submits that, although the Examiner is correct in stating that the original disclosure describes a range of pore sizes that can be used on the membrane, the original disclosure indeed reasonably conveys to a person of skill in the art that the inventors had, at the time the application was filed, possession of the claimed intracranial aneurysm stents comprising a membrane of substantially uniform porosity. Accordingly, Applicant respectfully requests withdrawal of the written-description rejection of claims 1-13, 15-22, 24-36, and 39-40.

35 USC § 112, Second Paragraph

The Examiner rejected claims 1-40[2] as allegedly indefinite, stating:

> *Claims 1 and 34 disclose that the pores are uniform, that the blood cannot pass to the aneurysm through the membrane, and that blood cannot pass through the membrane into branch vessels.*
>
> *It is unclear to the examiner how blood cannot pass through a portion, but can pass through another portion of the membrane if the pores are uniform.* (Office Action, page 3.)

Amended claims 1 and 34 recite a medical device that comprises a porous membrane having a substantially uniform porosity over a length extending from a distal end of the membrane to a proximal end of the membrane; and, when the mechanically expandable device(s) is (are) expanded in a bodily vessel, adjacent to a intracranial aneurysm, the membrane is effective to: (i) obstruct blood flow from the vessel into the aneurysm such that blood flow is substantially not allowed into the aneurysm; and (ii) permits blood flow through pores in the membrane and into perforators (or microscopic branch vessels) of brain arteries. Support for the amendment to claim 1 is found in the specification at, for instance, page 15, lines 20-22.

Applicant submits it is well known that the amount and direction of blood flow between vascular regions that are separated by a porous membrane are determined by a number of factors, including the thickness of the membrane; the size, spacing, and density of the pores of the membrane; and the gradient in fluid pressure between each vascular region separated by the membrane. Applicant further submits that it is well known that, due to back pressure within an

[2] Applicant points out that claims 1-13, 15-22, 24-36, and 39-40 are pending. Applicant therefore proceeds as though the rejections under 35 USC §112 apply to claims 1-13, 14-22, 24-36, and 39-40.

intact intracranial aneurysm, blood pressure within the intact intracranial aneurysm is greater than blood pressure within a perforator vessel or a microscopic branch vessel arising from the (parent) artery from which the aneurysm arises.

Medical devices defined by the pending claims comprise a membrane of substantially uniform porosity. The porosity is selected such that blood flow is substantially not allowed from the intracranial artery in which the device is deployed, into the intracranial aneurysm that the device is deployed to treat. At the same time, due in part to the higher pressure gradient between (a) the intracranial artery and any perforator vessel (or microscopic branch vessel) arising from the intracranial artery, than between (b) the intracranial artery and the aneurysm, the selected membrane porosity permits blood flow into the perforator vessel (or the microscopic branch vessel) of the intracranial artery.

In view of the foregoing discussion, Applicant submits that pending claims 1-13, 15-22, 24-36, and 39-40 are not indefinite. Applicant therefore respectfully requests withdrawal of the indefiniteness rejection of pending claims 1-13, 15-22, 24-36, and 39-40.

Claim Rejections under 35 USC § 103

Rudakov and Fierens

The Examiner rejected claims 1-13, 15-20, 24-31, and 35-36 as allegedly obvious over Rudakov (USPN 6,451,050) in view of Fierens (USPAP 2002/0035394). (Office Action, pages 5-10.) Applicant respectfully traverses.

Patentable Weight

As a preliminary matter, Applicant notes that the Examiner states, in reliance upon In re Hutchinson, 69 USPQ 138 (CCPA 1946), that:

> *it has been held the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.* (Office Action, page 5.)

The Examiner also states, in reliance upon Ex Parte Masham, 2 USPQ2d 1647 (1987):

> *With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.* (Office Action, page 5.)

In the present Application, however, the recitation of independent claim 1 that the membrane, having a substantially uniform porosity, is effective to: (i) obstruct blood flow from the vessel into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into perforators of brain arteries when the device is expanded to treat an intracranial aneurysm, imposes a structural constraint, i.e., a structural capability requirement, on the membrane. Specifically, the membrane must obstruct blood flow from the vessel into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into perforators arising from the bodily vessel when the device is expanded in the bodily vessel adjacent the aneurysm. Because the "effective to" recitation of claim 1 is not merely a recitation of intended use, but confers structural limitations upon the claimed membrane, in the form of a structural capability requirement, the application of In re Hutchinson and In re Masham against claim 1 is inapposite. (See, e.g., Ex parte Kirk D. Prall, Appeal No. 2003-1556 (BPAI 2003), explaining that the recitation of "adapted to" is afforded patentable weight *when it imposes a capability requirement.*)

Rudakov

The Examiner asserts that Rudakov teaches all limitations recited in claim 1, except for the membrane having a substantially uniform porosity. (Office Action, page 5.)

Rudakov discloses expandable stent grafts for implantation in a human body vessel. (See, e.g., Abstract.) The stent grafts disclosed by Rudakov have a multilayered construction comprising an inner sleeve, an outer sleeve, and an a plurality of juxtaposed rings that form an intermediate layer. (See, e.g., Column 2, lines 1-7.) Rudakov discloses that the material used for the sleeves can be extended PTFE having pores of 10 μm to 90 μm in size, and a thickness of 0.001 to 0.008 inches. (See, e.g., Column 2, lines 9-30.)

But Rudakov is completely silent not only as to membranes having a substantially uniform porosity, but also as to, e.g., distances between membrane pores; aneurysms in general, intracranial aneurysms; intracranial arteries, perforator vessels, and microscopic branch vessels; and membranes having a substantially uniform porosity that, when deployed in treatment of a intracranial aneurysm, is effective to: (i) obstruct blood flow from the vessel into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into branch vessels arising from the bodily vessel.

Rudakov therefore fails to teach substantially more recitations of amended claim 1 than just a membrane having a substantially uniform porosity, as amended claim 1 recites a "medical device for insertion into a bodily vessel to treat an intracranial aneurysm, the device comprising: a mechanically expandable device, expandable from a first position to a second position such that, in the second position, an exterior surface of the mechanically expandable device engages with an inner surface of the vessel so as to maintain a fluid pathway through the vessel; and a porous membrane, expandable in response to expansion of the mechanically expandable device; wherein at least a portion of the membrane is secured to the mechanically expandable device, such that a proximal end of the membrane is proximate to a proximal end of the mechanically expandable device, and a distal end of the membrane is proximate to a distal end of the mechanically expandable device; and wherein the membrane has a substantially uniform porosity over a length extending from the distal end of the membrane to the proximal end of the membrane; and wherein, when the mechanically expandable device is expanded in the bodily vessel, adjacent to the aneurysm, the membrane is effective to: (i) obstruct blood flow from the vessel into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit

blood flow through pores in the membrane and into branch vessels arising from the bodily vessel."

Fierens

The Examiner states that Fierens discloses a mechanically expandable device with a membrane that contains a substantially uniform porosity, and asserts

> *it would have been obvious to a person having ordinary skill in the art to provide Rudakov with a uniform porosity in view of the teachings of Fierens, in order to promote cell growth as well as reducing the risk of embolic release through out the length of the device equally.* (Office Action, page 5.)

Fierens discloses expandable vessel stents, for reducing the risk of restenosis and thrombus formation, attached to a porous biocompatible material that may have pores of uniform density, size, and/or shape. (See, e.g., Abstract and paragraph 0024.) The stents disclosed by Fierens are indicated for use arteries and also in non-vascular lumens of the biliary ducts, the respiratory system, and the urinary tract. (See, e.g., Paragraph 0108.) The stents disclosed by Fierens are further indicated for use at bifurcations and branches of vessels. (See, e.g., Paragraph 0025.)

Fierens discloses that, when stenting a vessel bifurcation or branching, the radial opening of a stent may be positioned in line with the side branch to maintain the patency of the branch. (See, e.g., Paragraph 0026). Fierens also discloses that, when stenting a vessel bifurcation or branching with the radial opening of the stent positioned in line with the vessel, blood flow into a side branch will continue uninterrupted because the porous, biocompatible material of the membrane is permeable to blood flow. (See, e.g., Paragraph 0025.)

But Fierens is completely silent as to, e.g., distances between membrane pores; intracranial aneurysms; cranial arteries, perforator vessels, and microscopic branch vessels; and membranes having a substantially uniform porosity that, when deployed in treatment of a intracranial aneurysm, is effective to: (i) obstruct blood flow from the vessel into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through

pores in the membrane and into branch vessels arising from the bodily vessel. Fierens therefore fails to rescue many of the deficiencies in Rudakov's teachings regarding the medical device recited in amended claim 1.

Because the combination of Rudakov and Fierens, together with the knowledge of a person of ordinary skill in the art, fails to teach or suggest all the limitations of amended claim 1, the combination of Rudakov and Fierens fails to establish *prima facie* obviousness of amended claim 1. Furthermore, because claims 2-13, 15-20, 24-31, and 35-36 directly or indirectly depend from claim 1, those claims cannot be obvious over the combination of Rudakov and Fierens. Applicant therefore respectfully requests withdrawal of the obviousness rejection of claims 1-13, 15-20, 24-31, and 35-36 over Rudakov in view of Fierens.

Rudakov, Fierens and Solovay

The Examiner rejected claims 2, 5, 18, and 20-22 over Rudakov in view of Fierens and further in view of Solovay (USPN 5,769,884). Applicant respectfully traverses.

In the rationale for this obviousness rejection, the Examiner states:

> *Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of this of Fierens does not disclose that the distance between adjacent pores is from 40 to 100 microns. Solovay discloses that the distance between adjacent pores is from about 40 to 100 microns (Col. 2 Lines 51-55 and Col. 5 Lines 51-53). The pore size is between 30-120 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7) therefore the space between the pores is in the specified range. For example if the pore size is 30 microns than the space between the pores can be 90 microns. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified distance range between adjacent pores in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the*

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. (Office Action, page 12.)

For at least the above-indicated reasons, however, the combination of Rudakov and Fierens does not establish *prima facie* obviousness of amended claim 1, or any claim depending from claim 1. In addition, Solovay fails to rescue the deficiencies in the teachings of the combination of Rudakov and Fierens, regarding the medical device recited in claim 1.

Solovay discloses covered, expandable stents for treating stenotic regions of a blood vessel, the cover having different porosities (i.e., a nonuniform porosity) in different regions. In regions where tissue ingrowth and reendothelialization are desired, typically the end regions, the stent covering is more porous, and in those regions where it is desirable to inhibit such ingrowth, the stent covering is substantially non-porous. (See, e.g., Abstract and Column 1, lines 32-34.)

But Solovay is completely silent as to, e.g., intracranial aneurysms; cranial arteries, perforator vessels, and microscopic branch vessels; and membranes having a substantially uniform porosity that, when deployed in treatment of a intracranial aneurysm, is effective to: (i) obstruct blood flow from the vessel into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into branch vessels arising from the bodily vessel. Fierens therefore fails to rescue the deficiencies in the teachings of the combination Rudakov and Solovay regarding the medical device recited in claim 1.

Because the combination of Rudakov, Fierens, and Solovay, together with the knowledge of a person of ordinary skill in the art, fails to teach or suggest all the limitations of amended claim 1, the combination of Rudakov, Fierens, and Solovay fails to establish *prima facie* obviousness of claim 1. Furthermore, because claims 2, 5, 18, and 20-22 directly or indirectly depend from claim 1, those claims cannot be obvious over the combination of Rudakov, Fierens, and Solovay. Applicant therefore respectfully requests withdrawal of the obviousness rejection of claims 2, 5, 18 and 20-22 over Rudakov in view of Fierens and in further view of Solovay.

Dereume and Fierens

The Examiner rejected claims 34 and 39-40 as allegedly obvious over Dereume (USPN 5,948, 018) in view of Fierens. (Office Action, pages 15-18.)

Dereume

The Examiner asserts that Dereume teaches all limitations recited in claim 34, except for the membrane having a substantially uniform porosity. (Office Action, page 16.)

Dereume indeed discloses expandable stent grafts for implantation in a human body vessel. (See, e.g., Abstract). The stent grafts disclosed by Dereume comprise a support component and a cover, a liner or, or both a cover and a liner in the form of a stretchable wall material that is porous, elastomeric, and biocompatible in order to allow cellular invasion upon implantation, without stenosis, when the expandable and supportive graft is at its expanded diameter. (See, e.g., Abstract.) The endoluminal grafts disclosed by Dereume are indicated for use in branching blood vessels of the coronary vasculature; the peripheral vasculature; and other vessels, such as in the gastrointestinal system, the tracheobronchial tree, the biliary system, and the genitourinary system. (See, e.g., Column 9, lines 57-67.)

But Dereume is completely silent as to, e.g., distances between membrane pores; intracranial aneurysms; cranial arteries, perforator vessels, and microscopic branch vessels; and membranes having a substantially uniform porosity that, when deployed in treatment of a intracranial aneurysm, is effective to: (i) obstruct blood flow into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into perforators and/or microscopic branches of brain arteries when the device is expanded, to treat an intracranial aneurysm.

Dereume therefore fails to teach substantially more recitations of amended claim 34 than just a membrane having a substantially uniform porosity, as amended claim 34 recites, "a medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising: a first mechanically expandable device, expandable from a first

position to a second position such that, in the second position, an exterior surface of the first mechanically expandable device engages with an inner surface of a first branch vessel arising from a parent vessel so as to maintain a fluid pathway through the first branch vessel; a second mechanically expandable device, expandable from a first position to a second position such that, in the second position, an exterior surface of the second mechanically expandable device engages with an inner surface of a second branch vessel arising from the parent vessel so as to maintain a fluid pathway through the second branch vessel; and a porous membrane, at least a portion of a proximate end of the membrane is secured to the first mechanically expandable device and a distal end of the membrane is secured to the second mechanically expandable device; wherein the membrane has a substantially uniform porosity over a length extending from a distal end of the membrane to a proximal end of the membrane; and wherein, when the first mechanically expandable device is expanded in the first branch vessel adjacent to the aneurysm and the second mechanically expandable device is expanded in the second branch vessel adjacent to the aneurysm, the membrane is effective to: (i) obstruct blood flow into the aneurysm such that blood flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into perforators and/or microscopic branches of brain arteries when the device is expanded, to treat an intracranial aneurysm."

Fierens

The Examiner states that Fierens discloses a mechanically expandable device with a membrane that contains a substantially uniform porosity, and asserts:

> *it would have been obvious to a person having ordinary skill in the art to provide Dereume with a uniform porosity in view of the teachings of Fierens, in order to promote cell growth as well as reducing the risk of embolic release through out the length of the device equally.* (Office Action, page 17.)

As discussed above, Fierens is completely silent as to, e.g., distances between membrane pores; intracranial aneurysms; cranial arteries, perforator vessels, and microscopic branch vessels; and membranes having a substantially uniform porosity, that, when deployed in treatment of a intracranial aneurysm, is effective to: (i) obstruct blood flow into the aneurysm such that blood

flow into the aneurysm is substantially not allowed; and (ii) permit blood flow through pores in the membrane and into perforators and/or microscopic branches of brain arteries when the device is expanded, to treat an intracranial aneurysm. Fierens therefore fails to rescue many of the deficiencies in Dereume's teachings regarding the medical device recited in amended claim 34.

Because the combination of Dereume and Fierens, together with the knowledge of a person of ordinary skill in the art, fails to teach or suggest the medical device recited in amended claim 34, the combination of Rudakov and Fierens fails to establish *prima facie* obviousness of amended claim 34. Furthermore, because claims 39 and 40 depend from amended claim 34, those claims cannot be obvious over the combination of Rudakov and Fierens. Applicant therefore respectfully requests withdrawal of the obviousness rejection of claims 34 and 39-40 over Dereume in view of Fierens.

Discussion of New Claims

New claims 41-76 are similar to claims 1-13, 15-22, 24-36, and 39-40. But, unlike independent claims 1 and 34, independent new, independent claims 41 and 72 do not recite "effective to" language. In addition, claims 42-71 and 73 directly or indirectly depend from claim 41 and claims 74-76 depend from claim 72.

No new matter has been added.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests favorable action on this application. If any questions remain, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

Any remarks in support of patentability of one claim should not necessarily be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not necessarily be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully reserves the right to traverse any of the Examiner's rejections or assertions, even if not discussed herein. Applicant respectfully reserves the right to challenge later whether any of the cited references are prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant reserves the right to contest later whether a proper reason exists to combine prior art references.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203, and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

James W. Hill, MD
Registration No. 46,396

18191 Von Karman Ave., Suite 500
Irvine, CA 92612-7108
Phone: 949.851.0633
Facsimile: 949.851.9348
Date: February 26, 2009
JB:gmb
ORC 456721-1.077567.0021

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